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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/036,150 | 12/26/2001 | Luc Desnoyers | P3030R1C9 | 4456 |

7590 09/26/2006

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EXAMINER

HAYES, ROBERT CLINTON

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1649

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------------------|---------------------------------|--|
| Office Action Summary | Application No. 10/038,150 | Applicant(s) DESNOYERS ET AL | |
| | Examiner Robert C. Hayes, Ph.D. | Art Unit 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30, 32-34 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27, 30 and 38-41 is/are rejected.
- 7) ☒ Claim(s) 28, 29 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 12/9/05 has been entered.
2. The rejection of claim 35 under 35 U.S.C. 102(b) as being anticipated by Adams et al. (clone EST70856; Accession no. AA361388; April 21, 1997) is withdrawn due to the cancellation of this claim.
3. Applicant's arguments filed 12/9/05 have been fully considered but they are not deemed to be persuasive.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 28, 29 & 32-34 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. Claims 22-27, 30 & 36-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention, for the reasons made of record in Paper NOs: 20050321 & 20050908, and as follows.

In contrast to Applicant's arguments on pages 6-7 of the response, page 66 of the specification specifically describes only % identities to a "DNA molecule that encodes the same mature polypeptide encoded by any of the human protein cDNAs deposited with the ATCC" [emphasis added]. In other words, mix and matching % identities with fragments of the polypeptide of SEQ ID NO: 45 constitute new matter similar to the reasons previously made of record. Thus, Applicant's arguments are not persuasive for the reasons made of record, and as discussed during the interview of 11/17/05.

7. Claims 22-27, 30 & 38-41 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 20040902, 20050321 & 20050908, and as follows.

In contrast to Applicants' assertions on pages 7-8 of the response, no written description is provided in the specification for "any species other than human" of a PRO4405 molecule, in which disclosure of a single "human" polynucleotide sequence does not reasonably constitute "the claimed genus of polynucleotides"; especially as it relates to nucleic acids *having / comprising* fragments of any PRO4405 molecule. Moreover, nothing within Example 14 from the training materials states that a single human sequence is representative of such a genus.

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Therefore, consistent with that held by courts in *Vas-Cath*, *Fiers v. Revel*, *Univ. California v. Eli Lilly and Co.*, and *Fiddes v. Baird*, and for the reasons previously made of record, Applicant's arguments remain not persuasive.

To clarify the record, it is the Examiner's position that molecules of at least 95% identity to nucleic acids encoding the *mature* PRO4405 polypeptide with the recited functional language would reasonably constitute functional variants to the disclosed human sequence of SEQ ID NO: 44, and would encompass only "human" variant sequences; consistent with Examples 6, 7, 8, 9, 11, 13, 14 and especially Example 17 of the training materials. Again see also MPEP 2163.

It is further noted that Applicants' representative chose to ignore that agreed upon during the interview of 11/17/05, which should have placed this application in condition for allowance.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
February 23, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER